



NOV 19 2003

Thomas Hoxie
Novartis Pharmaceuticals Corporation
Patent and Trademark Dept.
564 Morris Ave.
Summit, NJ 07901-1027

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,521,184

#19

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,521,184, which claims the human drug product Gleevec® (imatinib mesylate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 586 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 586 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of November 18, 2002 (67 Fed. Reg. 69533). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,025) + 73 \\ &= 586 \text{ days}\end{aligned}$$

Since the regulatory review period began May 10, 1998, after the patent issue date (May 28, 1996), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,521,184
Granted	:	May 28, 1996
Original Expiration Date	:	May 28, 2013
Applicant	:	Jürg Zimmerman
Owner of Record	:	NOVARTIS CORPORATION
Title	:	Pyrimidine Derivatives and Processes for the Preparation Thereof

Classification : 514/252
Product Trade Name : Gleevec® (imatinib mesylate)
Term Extended : 586 days
Expiration Date of Extension : January 4, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter
Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read RE: Gleevec® (imatinib mesylate)
Acting Director Health Assessment Policy Staff, CDER FDA Docket No.: 02E-0024
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Patent Assignment Abstract of Title

Total Assignments: 3

Application #: 08234889 **Filing Dt:** 04/28/1994 **Patent #:** 5521184 **Issue Dt:** 05/28/1996
PCT #: NONE **Publication #:** NONE **Pub Dt:**

Inventor: JURG ZIMMERMANN

Title: PYRIMIDINE DERIVATIVES AND PROCESSES FOR THE PREPARATION THEREOF

Assignment: 1

Reel/Frame: 007767/0596 **Received:** 01/30/1996 **Recorded:** 01/02/1996 **Mailed:** 04/22/1996 **Pages:** 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: ZIMMERMANN, JURG

Exec Dt: 04/08/1994

Assignee: CIBA-GEIGY CORPORATION

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Assignment: 2

Reel/Frame: 011979/0294 **Received:** 07/19/2001 **Recorded:** 07/03/2001 **Mailed:** 09/21/2001 **Pages:** 4

Conveyance: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

Assignor: CIBA-GEIGY CORPORATION

Exec Dt: 12/31/1996

Assignee: NOVARTIS CORPORATION

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Assignment: 3

Reel/Frame: 011089/0648 **Received:** 10/11/2000 **Recorded:** 08/22/2000 **Mailed:** 11/14/2000 **Pages:** 5

Conveyance: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

Assignor: CIBA-GEIGY CORPORATION

Exec Dt: 06/12/1997

Assignee: NOVARTIS CORPORATION

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If you have any comments or questions concerning the data displayed, contact OPR / Assignments at 703-308-9723
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